ARIZONA BOARD OF OSTEOPATHIC EXAMINERS

IN MEDICINE AND SURGERY

In the Matter of: DAVID L. PAYNE, D.O., Holder of License No. 1640 for the Practice of Osteopathic Medicine and Surgery in the State of Arizona.	Board Case No. 1742; Office of Administrative Hearings No. 95-002-OST FINDINGS OF FACT, CONCLUSIONS OF LAW AND BOARD ORDER

INTRODUCTION:

This matter came before the Board of Osteopathic Examiners (hereafter, "Board") for final consideration and decision at the Board's public meeting held on August 7, 1996. Pursuant to its statutory authority at A.R.S. § 32-1855(F), the Board issued its formal complaint in this matter on October 4, 1995. Subsequently, the matter was assigned to the Board's designated hearing officer, Harold Merkow, Administrative Law Judge; and, evidentiary hearings were conducted before Administrative Law Judge Merkow on April 1, May 3 and May 6, 1996 in Phoenix, Arizona. Thereafter, Administrative Law Judge Merkow issued and submitted to the Board proposed Findings of Fact, Conclusions of Law and Recommended Decision.

During the course of these proceedings, David L. Payne, D.O. (hereafter, "Respondent") was represented by John H. Lyons, Attorney and the State was represented by Michael N. Harrison, Assistant Attorney General.

Based upon the report submitted by Administrative Law Judge Merkow, and the documentary evidence submitted to the Board and the testimony received during the administrative hearings, the Board issues the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

1. Respondent is the holder of License No. 1640, authorizing him to engage in the practice of osteopathic medicine in the State of Arizona.

2. Respondent has a family medical practice in Mesa, Arizona. A significant portion of his patient census consists of HIV positive patients who he regularly treats.

3. In addition to standard therapies used to treat HIV positive patients, Respondent is willing to refer patients to and provide alternative, unconventional and experimental therapies to his HIV positive patients. Respondent has been a participant in drug-company sponsored experimental studies where he has used the companies' protocols to offer experimental therapies to his patients.

4. In August 1993, one L.B. became a patient of Respondent's. L.B. was, at the time, a 40 year old female who resided in Flagstaff and who was HIV positive for approximately nine years. At the time Respondent began treating L.B., her T-cell count was about 30. L.B. had been receiving treatment from other medical facilities and physicians and she started seeing Respondent because she had been told that Respondent was willing to provide alternative treatment therapies to his patients. L.B. visited Respondent's office on a monthly basis thereafter.

5. Sometime in the summer of 1993, Respondent met one David Hudson who offered an alternative therapy for Respondent's patients that Hudson told Respondent consisted of "monoatomic orbitally rearranged iridium and rhodium". Hudson showed Respondent some technical articles from scientific journals about superconductivity and activation energies, nonlinear properties of coherent electrical vibrations in living cells, spectrometry, quantum effects in rapidly rotating nuclei, microclusters and the like. Hudson explained to Respondent that he, Hudson, had discovered a method of extracting "monoatomic orbitally rearranged iridium and rhodium" from aloe vera plants and that the "monoatomically orbitally rearranged iridium and rhodium" would remain in a high spin

state indefinitely. Hudson told Respondent that he had also extracted white powder gold which had medicinal value according to alchemy texts and he wanted Respondent to try his "monoatomically orbitally rearranged iridium and rhodium" to see whether it would have therapeutic value in Respondent's patients.

6. Respondent read the articles Hudson showed him, although Respondent was not provided with copies of the articles by Hudson. Respondent also arranged to conduct a tour of Hudson's facilities. Respondent did not question Hudson about his scientific credentials or about any manufacturing standards that were in place to preserve sanitation and sterility.

7. In fact, Hudson has no scientific training in molecular physics or advanced chemistry. The manufacturing facilities for the production of his substance are located in a building on a farm in Laveen, Arizona where Hudson resides.

8. Respondent went to Hudson's Laveen manufacturing plant. However, Respondent was not permitted to see the manufacturing area as Hudson had told him that the process for extracting "monoatomically orbitally rearranged iridium and rhodium" was proprietary. Respondent was able to see the front area of the building and he noticed an autoclave and a laminar air flow hood on the premises.

9. Hudson told Respondent that the "monoatomically orbitally rearranged" rhodium and iridium was undetectable by conventional analytical equipment but he represented to Respondent that the "monoatomically orbitally rearranged" iridium and rhodium had been identified by Argon National Laboratories. No written confirmation of that representation was sought by Respondent and none was voluntarily provided by Hudson.

10. Hudson told Respondent that the source of discovery for the "monoatomically orbitally rearranged" iridium and rhodium was an alchemy textbook that he had read and that he, Hudson, had been using the substance on cancer patients. No

written evidence of treatment of any patient using the Hudson substance were sought by Respondent and no evidence showing any treatment using the Hudson substance by any person was offered by Hudson.

11. Respondent agreed to test Hudson's "monoatomically orbitally rearranged" iridium and rhodium on an animal and Hudson provided vials of his substance to Respondent. Respondent learned about a dog which had a large stomach abscess and was suffering from valley fever and he offered to use the Hudson substance to treat the dog. Respondent injected Hudson's substance in the dog over a period of time and, after such injections, Respondent observed that the abscess had shrunk and the valley fever symptoms disappeared.

12. Respondent reported his findings to Hudson and the two of them remained in regular communication, ordinarily by telephone.

13. In November or December 1993, Respondent provided the Hudson substance to another of his HIV positive patients who was then suffering from Kaposi's sarcoma and who had large lesions in his mouth and throat. The substance was administered intravenously through a central line which had been established earlier. Although the patient had an infection at the site of the central line, after several injections of the Hudson substance, Respondent noted that the Kaposi's sarcoma lesions were shrinking and disappearing.

14. In the latter part of 1993, L.B. was psychologically depressed. However, her physical condition was relatively normal, despite the HIV infection. As her husband described her "she was carrying on life as usual. She was tired, but she carried on. She did what people normally do and then some".

15. In either November or December 1993, Respondent introduced L.B. to Hudson's substance and L.B. began taking 50 mg. capsule doses of the substance orally, which capsules L.B. received from Respondent. Sometime earlier, Hudson had prepared

the capsules and given them to Respondent. Prior to agreeing to use the substance, Respondent had told L.B. and her husband about his success with the sick dog and with another HIV patient who was doing well and he encouraged the patient to discuss the substance with Hudson. At the time Respondent discussed the Hudson substance with L.B., her T-cell count had declined to 10 although she was not showing symptoms of AIDS and had not been attacked by any opportunistic infections.

16. Respondent told L.B. and her husband that the substance was prepared by a chemist, that he was relying on Hudson's representations about the substance and he told them that he had visited the facilities where the substance was manufactured where he had seen an autoclave and hood. Respondent did not seek to have L.B. sign an informed consent prior to her use of the Hudson substance. Respondent did not provide any literature to L.B. and her husband about the substance.

17. L.B. and her husband discussed the oral use of the substance with Hudson approximately six or seven times while L.B. was taking the capsules of Hudson's substance trying to get information about the substance. Hudson repeatedly told L.B. and her husband about a diabetes patient who was using the substance and doing better because of it. Other discussions included the number of people using the substance and L.B.'s husband concluded that ten to twelve people were using the substance.

18. After using the Hudson substance orally for approximately 30 days without any effective response, Respondent discussed with L.B. the possibility of having the substance administered intravenously. Respondent told L.B. and her husband that he had been using the substance intravenously in a patient with Kaposi's sarcoma and in a veterinary case, both with good results. Respondent told L.B. that a PICC line could be established in her arm for the administration of the Hudson substance and L.B. agreed to take the Hudson substance intravenously through a PICC line. Respondent did not seek to have L.B. sign an informed consent for using the Hudson substance intravenously.

19. Prior to establishing the PICC line, Respondent had explained to L.B. that, if she used the substance intravenously, because it had immune system stimulation properties, she should expect to experience 'flu-like' symptoms.

20. No entries exist in L.B.'s patient records to show that Respondent discussed the extent of his knowledge about the identity of the Hudson substance constituents, that Respondent disclosed the extent of his knowledge about any medicinal properties of the substance, that Respondent disclosed the extent of his knowledge about the manufacture of the substance or that Respondent explained any risks to L.B. in using the substance. No notations exist in the patient records to show that Respondent even provided the capsule form of the Hudson substance to L.B.

21. On January 31, 1994, Respondent's infusion nurse, Maryanne 'Mitzi' King, met with L.B. and explained the PICC line to her. On Monday, February 7, 1994, in Respondent's office, King established the PICC line in L.B.'s left arm. L.B. and her husband were instructed on the care and maintenance of the PICC line by King. Before leaving to return to Flagstaff, Respondent gave L.B. and her husband two six-inch long tubes containing a "brownish, gray-brown" solution which solution he had been keeping at room temperature and which solution Respondent represented to be the Hudson substance consisting of "monoatomic orbitally rearranged" rhodium and iridium. The tubes contained particulates that settled to the bottom of the tubes when the tubes were not agitated. L.B. was instructed to administer a 2 cc. dose of the solution through the PICC line and it was expected that the injections would occur at L.B.'s home in Flagstaff. No written instructions about the care of the PICC line, about administration of the substance or about storage of the substance were provided to L.B. by Respondent.

22. No evidence exists in Respondent's patient records for L.B. showing that a PICC line was inserted on February 7, 1994, that Respondent gave two tubes of the Hudson substance to L.B., that Respondent provided any written or oral warnings to L.B.

about the risks of using the Hudson substance, that L. B. was trying an alternative form of therapy or what, if anything, Respondent expected from L.B.'s use of the Hudson substance.

23. L.B. and her husband returned to Flagstaff on February 7, 1994 with the two tubes of the Hudson substance in solution. Because the PICC line bled for several hours after insertion, no injection of the Hudson solution was provided to L.B. on that date.

24. In the afternoon hours of Tuesday, February 8, 1994, L.B.'s husband, in preparation for giving an injection of the Hudson substance, shook one of the tubes, inserted a syringe needle through the rubber stopper and withdrew 2 ccs. of the Hudson substance solution which he injected through the PICC line into L.B.'s arm. The syringe was from a box of disposable syringes that was kept at their home. Within a few hours, L.B. began experiencing nausea, sweats and a fever. L.B.'s husband took her temperature for an extended time and, at least one time, the fever reached 105°. L.B.'s husband tried to reach Respondent by telephone but Respondent was not available to speak with him. L.B.'s husband also called David Hudson to tell him about the symptoms L.B. was experiencing who assured him that there was nothing to worry about.

25. On the following day, February 9, 1994, Respondent spoke with L.B.'s husband. The husband told Respondent about the fevers and Respondent informed him that the symptoms were to be expected because of the immune response of the substance but, to be careful, L.B. should have a blood culture done. Respondent also told L.B.'s husband that, if L.B. intended to use the substance again, they should wait at least one day and then cut the dosage by half.

26. Respondent telephoned L.B.'s primary care physician and requested that he draw blood for a culture. L.B. went to the physician's office on February 10, 1994 and blood was drawn from her right arm, the opposite arm from the PICC line. Even though

Respondent wished to have blood drawn from the PICC line, the technician was not certified to perform that procedure and the blood was therefore drawn from L.B.'s other arm.

27. The blood was sent to a laboratory for culturing and, at both 24 hours and 48 hours, no growth was detected.

28. Between the time L.B. experienced symptoms following the first injection until Thursday of that week, she continued to be nauseous and have fevers. By Friday, she was feeling well again.

29. On Saturday, February 12, 1994, L.B. was administered a 1 cc dose of the Hudson substance by her husband through the PICC line. Within two hours, she began having fevers, chills and nausea and, about three hours after the injection, her skin became clammy, she became unconscious and had respiratory arrest. L.B.'s husband called 9-1-1 and L.B. was rushed to Flagstaff Medical Center where she was later admitted to the intensive care unit.

Although her seizures diminished, she did not regain consciousness and two days later was transferred to University Medical Center in Tucson.

30. Shortly after L.B.'s admission to Flagstaff Medical Center, L.B.'s husband telephoned Respondent and left a message at Respondent's home in Strawberry, Arizona informing him that L.B. had been transferred from their home to the hospital after suffering seizures. Respondent retrieved the message from his answering service and then proceeded to Flagstaff Medical Center on the same date. When Respondent arrived, he asked L.B.'s husband whether he had the tube containing the Hudson substance and L.B. said that he thought that it was still at home. L.B.'s husband left the hospital and returned sometime later with the tube from which the injections had been given. L.B.'s husband gave the tube to Respondent because Respondent told L.B.'s husband that he wanted to have laboratory work done on the tube's contents. The whereabouts of the tube are

unknown to this date. No laboratory reports from the contents of the tube have been produced to date.

31. While at the hospital, Respondent was asked about L.B.'s treatment and he told hospital personnel that L.B. had received an intravenous injection of "monoatomic orbitally rearranged" iridium and rhodium.

32. On the following day, L.B.'s husband retrieved the second vial of the Hudson substance from his home and gave the vial to personnel at the Flagstaff Medical Center.

33. The contents of the second vial were analyzed and two forms of gram negative bacteria were isolated, pseudomonas and flavobacterium, each of which produces endotoxins that can cause sepsis.

34. On the day of admission to Flagstaff Medical Center, hospital personnel contacted the Poison Control Center in Tucson about L.B.'s intake of iridium and rhodium. One Leslie Boyer, the Poison Control Center toxicologist, contacted the hospital on the following day, seeking information about the substance that was administered to L.B. She spoke with nurse Linda Griffith who told her that the laboratory at the hospital had obtained a vial of the substance and would be testing it. When she described the testing procedures, Boyer told Griffith that the hospital was culturing the vial to see whether it was contaminated with germs or endotoxins. Boyer was then transferred to the pathology lab where the contents of the unlabeled, red capped container that appeared to be a plain tube of the type that is used to send samples to a laboratory were described as "this whitish-looking stuff in it that looks like you might have gotten it at a dirty pond or something. It's real scary looking". Boyer directed the personnel to keep the vial locked as it may end up being legal evidence. Boyer then spoke with the hospital pathologist, Dr. Forrest Ritland, who told Boyer that the tube was labeled "iridium infusate/mixed ORMES" and that it looked like it contained a fine gray 'sand' at

the bottom of the container which had precipitated out which, when shaken, turns milky. Boyer offered to have the materials tested at the University of Arizona where they had analytical processes to qualitatively and quantitatively detect heavy metals, including GC mass spec, Electron Dispersive Analysis of x-rays (EDAX) and proton induced x-ray emission (PIXE) scan. A portion of the tube's contents was then prepared for shipment to Dr. Boyer.

35. On February 13, 1994 at 5:45 P.M., Dr. Boyer spoke with Respondent. When asked what L.B. had been given, Respondent replied that "the iridium is just a metallic element. It's just a mineral substance, just in the same category as gold and platinum" in "monoatomic form. It's just in, it's not in an solid form, it's orbitally rearranged monoatomic element. It has a high spin state in the outer orbit and so it's just single atoms of iridium". Respondent then told her that the solution contained both iridium and rhodium and that L.B. received ½ mg. of each in the dosage that she received. When asked for literature about the use of iridium and rhodium, Respondent offered to FAX the literature that he had available, stating that "it's just basically along the same lines as cis-platinum or something. But it's monoatomic element and I'll send you what information I have on it and I will let you take a look at it". When asked about the manufacturer of the substance, Respondent replied "I can get the info. I really don't have it like right off the top of my head". Respondent also told Boyer that he had just spoken with the person who made the substance and that he had never seen anything of a cerebral problem with the substance. Respondent reiterated that he would get information to Dr. Boyer about the substance and the manufacturer.

36. On February 16, 1994, L.B. was transferred from the Flagstaff Medical Center to the University Medical Center in Tucson. A sample from the container was delivered to Dr. Boyer in Tucson and she gave the sample to one Quintus Fernando of the Department of Chemistry of the University of Arizona.

37. On February 15, 1994, Dr. Kellen Ronnau, M.D. filed a complaint with the Board against Respondent. In his complaint letter, Dr. Ronnau wrote: "Review of the literature shows no known use for Iridium. Consultation with various experts in infectious disease shown no known use for Iridium in treatment of HIV. Extensive evaluation of the patient revealed no other cause for her seizures and I feel it is related to the Iridium. At this time I would like to make a formal complaint for improper medical treatment with life threatening complications". On February 15, 1994, Dr. Boyer spoke with Dr. Fernando about his chemical analysis of the sample sent from Flagstaff. Dr. Fernando reported to Dr. Boyer that he had found titanium and zirconium but that no rhodium or iridium was present in the sample by testing the sample using x-ray fluorescence (XRF) and then by proton induced x-ray emission, (PIXE).

38. After speaking with Dr. Fernando, Dr. Boyer telephoned Respondent and told him that the sample contained zirconium and titanium but no iridium or rhodium. After explaining the analytical methodology to Respondent, Respondent told Dr. Boyer that "that is very bizarre". Dr. Boyer asked for Respondent's supplier of the substance and Respondent said he would contact her as soon as he could find him.

39. On that same day, February 15, 1994, Dr. Leslie Boyer wrote a letter of complaint to the Board, stating "My greatest concern is that other patients may have been provided with similar material for intravenous injection and that if this is the case that they must be warned against its' use before any further harm is done...it is not my habit to complain about experimental protocols which I have not had the opportunity to review formally; but in this case I am afraid for the safety of the people that may be involved". Dr. Boyer also wrote that "I reported the results of the chemical analysis to Dr. Payne today, and he expressed scepticism, indicating that the 'orbitally rearranged' nature of the elements involved would mask their identity on some assays. I reject this conclusion as nonsense and furthermore believe that even if the result were wrong there is ample cause

for alarm about whatever the product is. Dr. Payne has declined to name his chemical supplier, so I am at a loss to pursue this investigation further by way of Poison Control".

40. On February 17, 1994, Respondent telephoned Dr. Boyer and told her that he was now dealing with the Board and he asked for a report showing both qualitative and quantitative analysis. Respondent told Boyer that "this is going to become a very long issue that what was stated is there. Your chemists are not seeing it and they will never see it, I can tell you that. But what they do see is totally un-toxic and innocuous". Dr. Boyer asked Respondent about the process used to make the substance and Respondent replied "I don't know. It's just been patented, or it's in the process of being patented, he won't let me know anything more about how he does it, but he lets me know...I understand the physics, I have a degree in chemical engineering. I understand the physics of high-spin outer orbitals and how that works and why you don't see it on x-ray diffraction or x-ray fluorescence, or PIXE or any of those kinds of things. But it's in such minute amounts anyway that unless you know how to do the process, you're not going to find those things. But he somehow, he does something where he anneals it in a zirconium crucible, and then, I don't know what all else, but anyway, it's in such a minuscule amounts anyway that I'm not sure. It's basically homeopathic and that's the only thing he could say was that such minuscule amounts that they probably just didn't see it". Dr. Boyer then suggested that if Respondent has a preferred place to have it analyzed or method to have it analyzed or someone who understands the process and would care to make a recommendation that he prepare such a recommendation and that she would "endorse using whatever method you recommend".

41. There is no evidence in the record of this matter to show that Respondent furnished any literature to Dr. Boyer about the substance he provided to L.B.

42. There is no evidence in the record of this matter to show that Respondent, at any time, furnished the name and phone number of David Hudson to Dr. Boyer so that

Dr. Boyer could learn more about the substance Hudson provided to Respondent even though Respondent was in regular contact with Hudson during this period of February 1994.

43. There is no evidence in the record of this matter to show that Respondent ever recommended a place, method or person to Dr. Boyer for analysis of the Hudson substance in order to learn the identity of it.

44. On March 24, 1994, L.B. died while a patient at University Medical Center. She never regained consciousness from the time she was admitted to Flagstaff Medical Center to the time she died. An autopsy was performed and the final anatomic diagnoses of the pathologist were: 1) Acute bilateral polymicrobial bronchopneumonia secondary to aspiration; 2) staphylococcus aureus sepsis with shock a) centrilobular hepatic necrosis b) acute renal tubular necrosis; 3) HIV positive a) lymphoid depletion of spleen and lymph nodes; and 4) s/p injection of unknown therapy inducing coma of 4 weeks duration a) severe anoxic encephalopathy.

45. The Board thereafter began an investigation into the complaints of Drs. Ronnau and Boyer.

46. Shortly after L.B.'s death, her family filed a civil suit against David Hudson and later Respondent.

47. In connection with the civil lawsuit, the deposition of David Hudson was taken. In his deposition taken on May 13, 1994, he explained the initiation of his contact with Respondent. He testified that he had approached one Sue Dodd, his next door neighbor, who gave Respondent's name to Hudson as "one of the most caring and the most sensitive to the issue of AIDS and that he would be the one I ought to talk to about the material". Hudson further testified that he approached Respondent because "I was of the opinion that it might have medicinal characteristics. I had become aware of information that said it had medicinal characteristics and I took it to the doctor because I

felt the doctor would best decide what should be done with the material". Hudson explained that his belief in the medicinal characteristics of the material was based on a book on alchemy that said that the white powder of gold was medicine and was "a cure for all diseases known to man", which book he discussed with Respondent at their initial meeting. Hudson further explained the medicinal uses for his substance by referring to the *Platinum Metals Review* which, Hudson indicated, used platinum, rhodium, iridium and gold in the treatment of cancers "all over the world" and that "their understanding of the way it works is — this is the subject of many of the papers — is that this material interreacts with the DNA, correcting the DNA, causing the DNA to relax and recombine corrected so it no longer is cancer. It actually is a corrected DNA. So that the cell replicates itself, it replicates itself as a healthy T cell, not as a cancer cell. And so based on this knowledge, what we are doing with or what we are proposing to do is to use the elemental forms of these elements to interreact with the DNA correcting the DNA". Hudson further testified that "The way this — it appears that what is going on at this time — how is this curing this AIDS problem? It does not chemically react with anything in the body, yet it appears to change the DNA to the correct form. The conclusion of the people in medical research is that these elements resonance connect by a vibrational wave the light to the cell correcting the cell. We must assume that it then is interreacting with this cell and correcting this cell. This is exactly what the alchemical substance is supposed to do. It's supposed to perfect every cell in the body; okay? This is what it claims to do. And that's what the material appears to be doing. I find this extremely intriguing because there are a couple of other things that the stuff is supposed to do that we haven't gotten to yet. Q. Like what? A. The gift of perfect telepathy. You're supposed to be able to read the hearts and minds of others".

48. In a further deposition taken of Hudson on July 19, 1994, Hudson testified that, after learning of the symptoms experienced by L.B. after taking the substance, he

researched the discovery of titanium and zirconium in the samples taken and that "other than the little bit of nausea and some flu-like symptoms going on, the administration of these elements — there is nothing associated with seizures or anything of that nature...and you know, the levels we were administering of two milligrams of total material in two cc's of water, two milligrams of titanium and zirconium was a microgram amount and would not have been — it would not — could not have possibly caused what symptoms this lady experienced". When asked to describe the process for obtaining "monoatomic" elements, Hudson testified that an ore from "hydrothermal volcanic activities about 65,000 years ago" commonly found in the Southwest is used, which ore contains the "monoatomic" state of rhodium and iridium which is extracted through a chemical process and which instrumental analysis will not detect even though one is able to hold the substance in one's hand, "but it can be identified colorimetrically by forming chlorides of it and then analyzing the spectral lines of the chlorides. But there's no direct ionization spectrum, no emissions spectrum and no nuclear spectrum that will equate metals. Because metals are not elemental. The metals are metals".

49. The Board continued its investigation into the matter and, on August 5, 1995, the Board conducted an informal interview concerning the matter.

50. In the informal interview, the Board's consultant, Peter McKellar, M.D., an infectious disease specialist, told the Board that he had no objection to the use of alternative therapies in HIV positive patients but that the manner in which the alternative therapy was delivered that "really bothers me". Dr. McKeller criticized the manner in which the substance was administered, stating "When you're going to do something like this, you really ought to do it, particularly if you're doing it in the name of science, you ought to do it with some regard towards the circumstances in which it's being done. You should have the patient observed carefully. You shouldn't be unclear as to what's being infused, and certainly you need to know the sterility of the substance being infused...So

I'm bothered that there was no quality assurance on this material, that there was not written protocol as to what was going on and what was going to be looked for to see if there was a benefit, and that there was no signed informed consent, which I think is very important. I personally think that if this patient wanted to have something instilled into her vein in the name of maybe saving her, in the hope of maybe saving her, and she understood the risks and they were carefully explained and outlined and written, and she signed and it was witnessed, that's her prerogative. I don't have trouble with that. I'm bothered, though, when it's done as it was done in this setting where a vial of questionable substance or questionable sterility was handed to the patient and husband and they then were also given, or the patient was given an intravenous line in the doctor's office and told that when you get back to Flagstaff use it. That's not the way you do this kind of thing. That to me is well below standards of care. This was not a research protocol; this was not an effort to study something and see if perhaps it would help. This was basically a shot in the dark done in a very inappropriate fashion". Dr. McKellar concluded that contaminants in the vial are what caused L.B.'s symptoms more so than heavy metals and that endotoxins produced from gram negative bacteria which then produced sepsis caused the distress to L.B..

51. Also testifying at the informal interview was Dr. Leslie Boyer, the toxicologist who had had conversations with Respondent during February 1994 and who had had the tube sample analyzed by Dr. Fernando. Dr. Boyer told the Board that the analytical equipment used by Dr. Fernando has the capability of detecting any metal with an atomic number greater than 20 on the periodic table and that, if iridium and rhodium were in the sample, they would have "come through loud and clear" but that neither metal was detected during the assays. Dr. Boyer also testified that, after describing Respondent's representation of the elements as monoatomically rearranged iridium and rhodium, Dr. Fernando told her that he thought that it was "nonsense" and that he could

not believe that anyone would believe that or use it as a basis for a pharmaceutical. Dr. Boyer also referred to a telephone call between Respondent and her on March 23, 1994 in which Respondent told her that an independent laboratory had shown iridium, rhodium, zirconium and titanium but that Respondent did not know the assay method or who did the assay. Dr. Boyer told the Board that, after review of the autopsy report, the quantitative analysis, the qualitative analysis and Dr. McKellar's information, her opinion was that the heavy metal content of the sample was low enough that any heavy metal toxicity would have been secondary to the effects of the organic or lower molecular phase of what was there and that she agreed that either an infectious agent or toxic by-product of an infectious agent would be responsible for the clinical observations seen in L.B. Dr. Boyer also expressed the opinion that, if L.B. had not had the two injections, she would not have become ill and died and "My interpretation as a consulting physician in her case is that whatever was in those vials made her sick and that that sickness went on to become death".

52. Respondent never provided any laboratory analysis to Dr. Boyer showing the presence of iridium, rhodium, titanium and zirconium in the Hudson substance after his conversation with her on March 23, 1994.

53. Also testifying before the Board at its informal hearing was Dr. Kellen Ronnau, the emergency room physician who initially treated L.B. Dr. Ronnau explained to the Board how he originally saw the tube containing the substance injected in L.B. and described it as "it looked like an amateur packaging job. It was to your typical commercial-type preparation that considered — since sterility is such an important issue here, I remember distinctly saying, you know, this looks like it was done in someone's basement". Dr. Ronnau opined that L.B. had been injected with a contaminated solution which caused sepsis. Dr. Ronnau also told the Board of his knowledge that Respondent obtained a vial of the solution from L.B.'s husband. Dr. Ronnau also told the Board that

he had had a conversation with Respondent on the night that L.B. was admitted, that Respondent told him that the solution was iridium, that it stimulates the immune system and that Respondent would send him "some papers on it" but that he never received any papers from Respondent.

54. The Board reconvened for an additional session of an informal interview of this matter on September 13, 1995 at which time Respondent testified. Respondent denied that he had received a vial of the Hudson substance from L.B.'s husband after he arrived at Flagstaff Medical Center.

55. Respondent also testified that the National Institutes of Health Alternative Therapies section was currently testing the monoatomic form of rhodium and iridium for HIV treatment and that a university, Bastyr University (identified in the transcript as Barter University) was also testing the substance, which information Respondent had heard approximately one month before. Respondent also told the Board that he tells his patients about "a number of alternative methods so that they may investigate themselves and, if they so desire, participate in them". In particular, L.B. was told by Respondent to contact David Hudson directly about using iridium and rhodium. When asked why he did not have the Hudson substance analyzed to assure that the vials were not contaminated, Respondent replied: "The supposition that the substance was not analyzable made it difficult for me to know here to go to get it analyzed as far as the substance goes, and it's also very expensive. I had also used the substance on a dog intravenously and he had had no problem with toxicity or contamination problems, and I have also seen Mr. Hudson's facility where he packaged the material and it looked like he was doing it properly".

56. Also testifying on September 13, 1995 was one John Garbutt, an ICU nurse at Flagstaff Medical Center who told the Board that he had seen one vial transferred from L.B.'s husband to Respondent, which vial Respondent placed in his jacket pocket. Garbutt also told the Board that he, Respondent, had later displayed the vial to the

pharmacist and himself by shaking the vial and declaring that it was a mineral and nothing more.

57. The Board voted the matter to formal hearing and a hearing was set to consider this matter, which hearing was later postponed and rescheduled to April 1, 1996. At the appointed date and time, Respondent appeared, together with Counsel.

58. At the April 1 hearing, the only other testimony presented by the Board in its case in chief to support its complaint was offered by Charles Secrist, pharmacist at Flagstaff Medical Center, who stated that, when told that patient L.B. had received iridium, he checked references and a computer program about the medicinal use of iridium and, when he could not find any such references, he called the Poison Control Center in Tucson. Secrist also testified that he saw a vial in Respondent's possession which vial contained a milky opaque fluid in it and that he had a discussion with Respondent at Flagstaff Medical Center.

59. At the hearing, in addition to Respondent's testimony, Respondent's presentation included testimony from Dr. Kenneth Fisher, Kirk Baxter and Robert Aronin, all of whom expressed support for Respondent. Also testifying was Mitzi King, the infusion nurse who inserted the PICC line into L.B.'s arm.

60. At the hearing, Respondent testified that he did not remember receiving a vial of the Hudson substance from L.B's husband on February 12, 1994.

61. No evidence exists in the record of this matter to show when, prior to February 1994, the Hudson substance that was delivered to L.B. by Respondent was manufactured or extracted.

62. No evidence exists in the record of this matter to show when, prior to February 1994, the Hudson substance was mixed with an aqueous solution prior to its delivery to Respondent in vials.

63. No evidence exists in the record of this matter to show how, prior to Respondent's receipt, the Hudson substance, either in solution or powder form, was stored.

64. No evidence exists in the record of this matter to show that David Hudson had any written procedures in place for the manufacture of his substance, which procedures would have been designed to guarantee sterility throughout the manufacturing process.

65. No evidence exists in the record of this matter to show that David Hudson had any written protocols in place to guarantee aseptic packaging of his substance.

66. No evidence exists in the record of this matter to show that David Hudson had any written protocols or procedures in place to guarantee sterility of his substance in storage.

67. No evidence exists in the record of this matter to show that David Hudson had any training in the manufacturing, processing or packaging of any substance in a sterile environment.

68. No competent evidence exists in the record of this matter to show that the Hudson substance delivered to Respondent in vials contained either iridium or rhodium, either in elemental form, in metallic form or otherwise.

69. No competent evidence exists in the record of this matter to show that the contents of a vial of the Hudson substance that was analyzed after February 12, 1994 contains any heavy elements other than iron, titanium and zirconium.

70. No credible explanation exists in the record of this matter for the existence or identification of a powdery, sand-like precipitate in the two vials of the Hudson substance delivered to Respondent.

71. No competent evidence exists in the record of this matter to show that the Hudson substance was ever scientifically analyzed to determine its properties, contents or

constituent elements other than Dr. Fernando's analysis performed after February 12, 1994 and the culture performed on the vial after L.B. entered Flagstaff Medical Center on February 12, 1994.

72. There is no competent evidence in the record of this matter to show that the Hudson substance was ever verified by the Argon National Laboratories to contain "orbitally rearranged monoatomic" rhodium or iridium.

73. No competent evidence exists in the record of this matter to show that any scientific analysis was attempted by John Sockifoose, Ph.D. to determine whether the Hudson substance contained "orbitally rearranged monoatomic" rhodium or iridium, or any other element in any form.

74. No competent evidence exists in the record of this matter to show that any scientific analysis was performed to show the presence of "orbitally rearranged monoatomic" forms of rhodium and iridium together with zirconium and titanium in Hudson's substance.

75. No competent evidence exists in the record of this matter to show that the presence of a powdery, sandlike precipitate in the bottom of the Hudson substance tube that was analyzed after February 12, 1994 is consistent with the presence of rhodium or iridium, or any other heavy element, in "monoatomic" form since individual atoms of either rhodium or iridium are not visible to the naked eye.

76. No competent evidence exists in the record of this matter to show that the contents of either vial of the Hudson substance given by Respondent to L.B. in February 1994 contains "orbitally rearranged monoatomic iridium and rhodium" that can correct or rearrange DNA into its proper form.

77. No competent evidence exists in the record of this matter to show that the Hudson substance delivered to Respondent in vials had the potential of any medical value for any purpose.

78. No competent evidence exists in the record of this matter to show that the Hudson substance delivered to Respondent in vials had any immunological augmentation or enlargement effect for any person infected with HIV.

79. No evidence exists in the record of this matter that the Hudson substance, either in powder or liquid form, has the power of perfect telepathy.

80. No scientific literature exists in the record of this matter to show that either rhodium or iridium, in any form, has any medicinal or healing powers. No scientific or medical literature exists in the record of this matter to show that iridium and/or rhodium have been used for any medicinal purposes.

81. No evidence exists in the record of this matter to show that either of the two vials Respondent received from David Hudson, claiming to contain "orbitally rearranged monoatomic" iridium and rhodium, were analyzed by Respondent for purity or contents, prior to Respondent's delivery of the two vials to L.B. in February 1994.

82. No evidence exists in the record of this matter to show that, after L.B. injected the Hudson substance on February 8, 1994 and thereafter suffered extreme 'flu-like' symptoms, Respondent sought to have the contents of the vial used for L.B.'s injection analyzed for purity and sterility.

83. No evidence exists in the record of this matter to show that, after receiving one of the two vials from L.B.'s husband on February 12, 1994, Respondent undertook to have the vial analyzed for purity or contents.

84. No competent evidence exists in the record of this matter to show that the contents of the two vials containing the Hudson substance that Respondent gave to L.B. in February 1994 were safe or effective for intravenous injection.

CONCLUSIONS OF LAW

1. This matter is within the jurisdiction of the Arizona Board of Osteopathic Examiners in Medicine and Surgery pursuant to A.R.S. §, §32-1801 et. seq. and the

regulations promulgated thereunder.

2. Respondent's actions in failing to document in his patient records the administration to L.B. of the Hudson substance, in either capsule form or intravenously, despite having provided her with the substance in both forms from stocks he maintained in his office, constitutes a violation of A.R.S. §, §32-1854 (21).

3. Respondent's actions in failing to document in his patient records that he advised L.B. of the risks of using the Hudson substance, in either capsule form or intravenously, constitutes a violation of A.R.S. §, §32-1854 (21).

4. Respondent's failure to document in his patient records for L.B. that L.B. understood the risks of using the Hudson substance and that she was proceeding with the use of the substance notwithstanding such risks constitutes a violation of A.R.S. §, §32-1854 (21).

5. Respondent's failure to include an informed consent, signed by L.B., acknowledging the risks of using the Hudson substance, constitutes a violation of A.R.S. §, §32-1854 (21).

6. Respondent's failure to independently examine the truth of any statement made by David Hudson regarding the sterility under which the Hudson substance was packaged, stored and delivered to Respondent when Respondent knew, or should have known, that Hudson had no formal scientific or medical training and that no protocols for sterility were maintained by Hudson constitutes a violation of A.R.S. §, §32-1854 (40).

7. Respondent's failure to independently examine the truth of any statement made by David Hudson regarding the sterility under which the Hudson substance was manufactured, extracted, prepared, stored and delivered to Respondent when Respondent knew, or should have known, that Hudson had no training in manufacturing, processing and packaging in a sterile environment constitutes a violation of A.R.S. §, §32-1854 (40).

8. Respondent's failure to investigate the truth of any statement made by David Hudson about the proprietary production method of "orbitally rearranged monoatomic rhodium and iridium", including his failure to obtain any patent application represented by Hudson to exist, including his failure to obtain reports from Argon National Laboratories which Hudson represented to exist and including his failure to obtain any laboratory analyses performed by Hudson himself constitutes a violation of A.R.S. §, §32-1854 (40).

9. Respondent's failure to investigate the truth of any statement made by David Hudson about the inability to analyze the Hudson substance using conventional state-of-the-art analytical devices, especially in light of Hudson's representations that the substance was analyzed by Argon National Laboratories, constitutes a violation of A.R.S. §, §32-1854 (40).

10. Respondent's failure to challenge David Hudson's assertions that he could manufacture "orbitally rearranged monoatomic rhodium and irridium", two of the rarest earth elements, from aloe vera plants or from volcanic ores, without documented proof of such ability, constitutes a violation of A.R.S. §, §32-1854 (40).

11. Respondent's actions in establishing a PICC line for L.B. in order to permit the intravenous injection of the Hudson substance in solution, without first verifying the safety and sterility of the substance that would be injected, constitutes a violation of A.R.S. §, §32-1854 (6) and (40).

12. Respondent's actions, after establishing a PICC line in L.B., whereby Respondent allowed L.B. to administer intravenous injection of the Hudson substance in solution at her home in Flagstaff, without any medical supervision and without first verifying the safety and sterility of the substance that would be injected, constitutes a violation of A.R.S. §, §32-1854 (6) and (40).

13. Respondent's actions in providing the Hudson substance to L.B. on February 7, 1994 for administration in intravenous injections, without first verifying that the substance contained what was purported to be "orbitally rearranged monoatomic rhodium and irridium" and that the substance would not harm the patient, constitutes a violation of A.R.S. §, §32-1854 (6).

14. Respondent's actions in referring L.B. to David Hudson for purposes of discussing his substance with him before deciding whether to use the Hudson substance, at a time when Respondent himself had not verified any of Hudson's representations about the manufacture, the contents, the storage or the sterility of the Hudson substance, constitutes a violation of A.R.S. §, §§32-1854 (6) and (40).

15. Respondent's failure to have the contents of one of the Hudson substance vials analyzed for purity and sterility after L.B. experienced extreme 'flu-like' symptoms following injection of the Hudson substance on February 8, 1994, when Respondent knew or should have known that the symptoms reported to him could have been immune system stimulating due to an infectious process occurring, constitutes a violation of A.R.S. §, §§32-1854 (6) and (40).

16. Respondent's failure to cede possession of the vial of the Hudson substance that was delivered to him at Flagstaff Medical Center so that the contents of the vial could be tested constitutes a violation of A.R.S. §, §§32-1854 (6) and (40) as, at that time, L.B.'s condition was unstable and an analysis of the contents of the vial could have provided material treatment information to her physicians.

17. Respondent's failure to submit any form of analysis on the contents of the Hudson substance tube that was delivered to him at Flagstaff Medical Center constitutes a violation of A.R.S. §, §32-1854 (6) and (40).

///

///

18. Respondent's failure to divulge Hudson's name and telephone number to Leslie Boyer so that Boyer could discuss the preparation of the substance directly with Hudson constitutes a violation of A.R.S. §, §§32-1854 (6) and (40).

19. Respondent's failure to provide Leslie Boyer with literature about "orbitally rearranged monoatomic rhodium and iridium", as he stated he would, and Respondent's failure to provide Leslie Boyer with the name or a laboratory which could test the Hudson substance for the presence of rhodium and iridium, as he stated he would, constitute violations of A.R.S. §, §32-1854 (15).

20. There is no credible evidence in the record of this matter on which to conclude that rhodium and iridium exist in nature in an "orbitally rearranged monoatomic" form which are capable of being extracted from either aloe vera plants or a 65,000 year old volcanic ore.

21. There is no credible evidence in the record of this matter on which to conclude that one can alter elemental rhodium and iridium to an "orbitally rearranged monoatomic" form that would exist in an indefinite state or for an indefinite time.

22. There is no credible evidence in the record of this matter that any laboratory or scientist has ever analyzed rhodium or iridium in an "orbitally rearranged monoatomic" form.

23. There is no evidence in the record of this matter showing that any university or public health agency has tested or experimented with rhodium or iridium, in any form, for medicinal purposes.

24. There is no credible evidence in the record of this matter on which to conclude that the National Institutes of Health or Bastyr University have undertaken any examination of or experimentation with "orbitally rearranged monoatomic" forms of rhodium and iridium.

25. There is no credible evidence in the record of this matter on which to conclude that the Hudson substance contains any "orbitally rearranged monoatomic" forms of rhodium and iridium.

26. There is no scientific evidence in the record of this matter on which to conclude that the Hudson substance contains rhodium or iridium, in any form.

27. There is no credible evidence in the record of this matter on which to conclude that the Hudson substance was manufactured using any recognized laboratory standards, using any recognized manufacturing standards or using any protocols to assure sterility.

28. There is no competent evidence in the record of this matter on which to conclude that the barn in which the Hudson substance was purportedly manufactured is capable of providing a sterile environment in which the substance could be manufactured, packaged and stored.

29. There is sufficient evidence in the record of this matter that the vials of the Hudson substance which were given to L.B. were contaminated with pseudomonas and flavobacterium bacteria, the endotoxins from which later created a septic condition in L.B. following her second infusion of the Hudson substance on February 12, 1994.

30. Respondent's actions in February 1994, whereby Respondent gave L.B. two vials of the Hudson substance, under circumstances whereby Respondent knew, or should have known, that the substance was manufactured, packaged and stored under conditions that could not reasonably assure an ordinarily prudent person that the substance was free from contamination, despite the presence of an autoclave and laminar air flow hood in the building on Hudson's farm in which the substance was purportedly extracted or manufactured, which later contamination of the substance led to L.B. going into a distressed condition on February 12, 1994 after being infused with two doses of the Hudson substance, once on February 8 and once on February 12, 1994, which distress was

caused by sepsis related to the contamination of the Hudson substance, constitutes a violation of A.R.S. §, §32-1854 (6) and (46).

31. Respondent's actions in February 1994, whereby Respondent gave L.B. two vials of the Hudson substance that had not been investigated by Respondent to determine whether they were free of contamination, which contamination led to L.B. going into a distressed condition on February 12, 1994 after being infused with two doses of the Hudson substance, once on February 8 and once on February 12, 1994, which distress was caused by sepsis related to the contamination of the Hudson substance, constitutes a violation of A.R.S. §, §32-1854 (46).

32. Respondent's actions in providing vials of the Hudson substance to L.B. in February 1994, which vials contained a purported experimental combination of minerals which were represented to correct DNA, whereby Respondent provided the vials outside of any generally accepted criteria for using experimental forms of therapy, constitutes a violation of A.R.S. §, §32-1854 (6) and (28).

33 . Respondent's actions in providing two vials of the experimental Hudson substance to L.B. in February 1994, without first obtaining any informed consent from the patient constitutes a violation of A.R.S. §, §32-1854 (28).

34. Respondent's negligent actions by accepting a substance from David Hudson that was purported to be of medicinal value, without first taking the elementary precautions of assuring himself of the safety and sterility of the product, regardless of any efficacy the substance may have had, constitute violations of A.R.S. §, §32-1854 (6), (40) and (46).

35. Respondent's testimony to the Board on September 13, 1995 where he denied receiving a vial of the Hudson substance from L.B.'s husband on February 12, 1994, which testimony was later recanted by Respondent to be a lack of recollection of

such possession, after three other people testified about Respondent's possession of the substance on February 12, 1994, constitutes a violation of A.R.S. §, §32-1854 (15).

36. Respondent's acts in violating A.R.S. §, §32-1854, which acts constitute unprofessional conduct, constitute grounds under which the Board may impose disciplinary action against Respondent pursuant to A.R.S. §, §32-1855(J).

ORDER

IT IS HEREBY ORDERED that the following disciplinary action is taken against David L. Payne, D.O., as follows:

1. Dr. Payne is censured for unprofessional conduct as more specifically described and defined in the previously set forth Conclusions of Law at paragraphs 2 through 36; and,

2. Dr. Payne is placed on probationary status for a period of five (5) years and ordered to comply with the following terms and conditions of probation:

> (A) Use only those recognized (i.e., by the Food and Drug Administration) experimental therapies for patient treatment and in compliance with recognized and standard protocols applicable to experimental therapies; and, Respondent may also use Food and Drug Administration ("F.D.A.") recognized experimental therapies for patient treatment in a manner not expressly approved by the F.D.A., if such treatment is medically justified and provided according to contemporary medical standards of care.
>
> (B) Commencing from the date of issuance of this Order, Dr. Payne shall obtain forty (40) hours of continuing medical education during the next two years (i.e., twenty hours for each year) concerning the topics of medical professional ethics generally and protocols governing the use of experimental therapies; and, Dr. Payne's selection of courses to satisfy this requirement shall be first approved by the Board, after Dr. Payne submits a description of the educational program he wishes to take in order to satisfy this requirement; and, upon completion of a seminar or course approved by the Board, Respondent shall submit to the Board's Executive Director documentation confirming his attendance and completion of the education program approved by the Board; and, this requirement for continuing medical education shall be <u>in addition to the minimum</u>

statutory requirement for renewal of Board license as specified at A.R.S. § 32-1825(B).

(C) After the effective date of this Order, Dr. Payne shall maintain all patient charts according to the "SOAP" format and additionally patient charts shall contain information regarding medications being taken by the patient (either prescribed or dispensed by Dr. Payne or another physician) and all experimental or "alternative" forms of therapy shall be noted in the patient chart; and, it shall be noted whether the experimental therapy is being provided by Dr. Payne or another individual; and,

(D) Before providing experimental forms of therapy to a patient, Respondent shall obtain a signed informed consent agreement from the patient; and Respondent shall retain the original copy of the consent agreement with the patient chart; and, the consent agreement shall fully describe the known or potential risks associated with the use of the experimental therapy and what, if any, representations are made regarding the desired therapeutic benefits that may be produced by the therapy.

(E) In order to assure compliance with this Order, the Board's staff physician shall conduct a review of patient charts and Dr. Payne shall cooperate in such review by providing those charts requested by the Board's staff physician; and, the staff physician shall report on whether the Respondent is in compliance with the terms of this probationary order for maintaining patient records or any other substantial issues regarding quality of care or other possible evidence of unprofessional conduct; and,

(F) When the Board schedules for its public meeting agenda a discussion of Board guidelines for the treatment and management of patients receiving experimental or alternative forms of therapy, Dr. Payne shall be informed of said meeting by the Board's executive director and requested to attend and participate in the Board's discussion; and,

(G) Respondent shall pay all costs arising from the Board's investigation, informal interview hearings and formal complaint proceedings concerning this matter (i.e., $12,122.74); and, payment of the costs shall be completed within five years from the effective date of this Order; and, Dr. Payne shall make quarterly payments (i.e., every three months with the first payment due on December 1, 1996) in equal installment amounts, but Respondent is not precluded from paying the total amount due at any time prior to the final date of payment.

(H) Every three (3) months during the probationary period, Dr. Payne shall report to the Board in either a written report or personal oral presentation to the Board, on the current HIV-AIDS research and current developments in the field of HIV-AIDS research; and, the Board through its executive director shall inform Dr. Payne regarding the date when the aforementioned reports shall be submitted and whether he should submit an oral or written report to the Board.

3. The Board's Executive Director shall promptly prepare and deliver copies of the Board's transcript of the informal interview hearing conducted with Dr. Payne on September 15, 1995 and the transcript of the administrative hearing conducted on May 6, 1996 and a copy of the Board's Findings of Fact, Conclusions of Law and Order to the appropriate criminal justice agency (i.e., Office of the Maricopa County Attorney, Criminal Division) to investigate evidence of possible criminal wrong doing, i.e., commission of perjury by Dr. Payne in regard to his testimony to the Board on September 15, 1995, that he did not receive a vial of the solution (originally delivered by Dr. Payne on February 7, 1994, to patient L.B.) from the husband of L.B. on or about February 12, 1994 at the Flagstaff Medical Center Hospital.

ISSUED AND EFFECTIVE this 26th day of September, 1996.

Board of Osteopathic Examiners
in Medicine and Surgery

Ann Marie Berger
Executive Director
141 E. Palm Lane, Suite 205
Phoenix, Arizona 85004

COPY mailed by U.S. certified mail (return receipt requested) this 26th day of September, 1996, to:

David L. Payne, D.O.
1050 E. University, Suite 3
Mesa, AZ 85203

COPIES mailed this 26th day
of September, 1996, to:

John H. Lyons, Attorney
30 W. First Street
Mesa, AZ 85201-6695

Michael N. Harrison
Assistant Attorney General
Civil Division
Office of the Arizona Attorney General
(Interagency Mail)

By: Karen L Pelley

mnh/pld/payne/findings/#1536